

ARCUATE™ Vertebral Augmentation System
510(k) Summary – K063248
February 2007

MAR 13 2007

I. Company: Medtronic USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

Contact: Christine Scifert
Group Director, Regulatory Affairs
(901) 396-3133

II. Proposed Proprietary Trade Name: ARCUATE™ Vertebral Augmentation System
Classification Name: Methyl Methacrylate for Vertebroplasty
Orthopedic Cement Delivery System, Tamp, Arthroscope
Product Code: NDN, KIH, HXG and HRX
Regulation No.: 888.3027, 888.4200, 888.4540 and 888.1100

III. Product Description/Purpose of Application

The purpose of this application is to notify the FDA of our intent to market the ARCUATE® Vertebral Augmentation System. The ARCUATE™ Vertebral Augmentation System consists of a variety of manual instruments which provide physicians with a means to augment the vertebral body with a mechanical device in order to prepare the site for vertebroplasty. Once the site is prepared, the ARCUATE™ Vertebral Augmentation instruments are used to percutaneously deliver polymethylmethacrylate (PMMA) bone cement to the spine. The ARCUATE™ Vertebral Augmentation System kits are packaged with and may only be used with VISIOPLAST™ Spine Cement, which has been cleared by the FDA for use in the treatment of painful vertebral compression fractures.

IV. Indications

The ARCUATE™ Vertebral Augmentation System is indicated for the treatment of painful pathological fractures of the vertebral body. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancers and myeloma.

V. Substantial Equivalence

Documentation was provided which demonstrated the ARCUATE™ Vertebral Augmentation System to be substantially equivalent to previously cleared systems such as the EQUESTRA™ Fluid Delivery System, (K040483, SE 06/23/04), the Kit Mendec Spine and Delivery System (Tecres SpA, K062452, SE 09/21/06), the EBI Vertebroplasty System (K060148, SE 03/13/06)

and the Vertefix™ Vertebroplasty Procedure Set, Cook Incorporated (K042691, SE 11/08/05).
The VISIOPLAST™ Spine Cement packaged with this system was cleared by the agency for use
in the treatment of vertebral compression fractures in K042415, SE 06/09/05.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

MAR 13 2007

Re: K063248
Trade/Device Name: ARCUATE™ Vertebral Augmentation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Methyl Methacrylate for Vertebroplasty
Regulatory Class: Class II
Product Code: NDN, KIH, HRX, HXG
Dated: February 7, 2007
Received: February 8, 2007

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

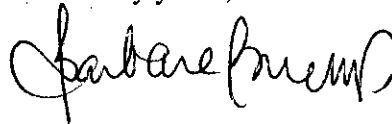
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 – Ms. Christine Scifert

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written in a cursive style.

Mark N. Melkerson,
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

February - 2007

510(k) Number – K063248

Device Name: ARCUATE™ Vertebral Augmentation System

Indications for Use: The ARCUATE™ Vertebral Augmentation System is indicated for the treatment of painful pathological fractures of the vertebral body. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancers and myeloma.

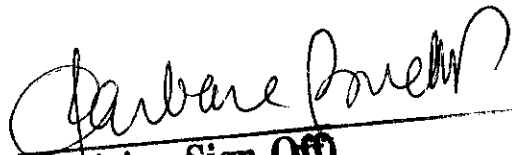
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063248